REMARKS

The Rejection of Claims 64-72 Under 35 USC §101 Should Be Withdrawn

The Examiner rejected claims 64-72 under 35 USC §101. The Examiner argued that the claimed invention is not supported by either a specific and substantial utility or a well-established utility. The Examiner stated that the utilities asserted in the specification "are not considered to be specific and substantial because neither the specification nor any art of record teaches what biological activities of SEQ ID NO:2 are, how they function, or a specific and well-established utility for SEQ ID NO:2 protein." The Examiner continued, "the specification fails to teach what kind(s) enzymatic reaction the protein carries out." In addition, the Examiner stated, "Until some actual and specific activity can be attributed to the SEQ ID NO:2 protein used in the claimed screening assay is incomplete."

Applicants respectfully traverse the rejection and submit that utilities for the polypeptides which are specific and substantial are in fact set forth in the specification. For example, at page 7, lines 9-10; at page 10, line 28 through page 11, line 14; in Figure 2; and at page 12, line 25, the specification teaches that the 62112 polypeptide is a human protein with an acyl-CoA dehydrogenase domain and acyl-CoA dehydrogenase activity. This is further supported by the studies of Zhang et al. (refer to citation C1 in Supplemental Information Disclosure Statement submitted on January 30, 2004). Zhang et al. described the cloning and characterization of 62112, which they designate acyl-CoA dehydrogenase 9, or ACAD-9 (see alignment of SEQ ID NO:3 and ACAD-9 (GenBank Accession No. BC013354, submitted herewith as Supplemental Information Disclosure Statement Citation No. C2) in Appendix A, showing 100% identity). Zhang et al. teach that 62112 is indeed a human acyl-CoA dehydrogenase, which exhibits acyl-CoA dehydrogenase activity (see Zhang et al., pages 1036-1037, paragraph spanning, and Fig. 5) especially towards stearoyl-CoA and palmitoyl-CoA. Thus, contrary to the Examiner's assertion, the specification does indeed teach what kind of enzymatic reaction the protein carries out, and this has been corroborated by others as evidenced by the teachings of Zhang et al. Therefore, the claimed methods pertain to specific molecules, with substantial and specific activities.

The Examiner also asserted that "the specification does not teach a relationship to any specific disease..." and, "does not teach a relationship between the different tissue distribution of the protein to any specific disease..." The Examiner added, "the implicit assertion of anticancer activity for the protein is not substantial."

Applicants respectfully disagree. For example, the specification at page 3, lines 25-36; at pages 86-90, and in Tables 1 and 2, for example, teaches that the 62112 dehydrogenase molecules can be used to treat cancer and tumors, including those arising from colon, breast, lung or ovarian cells, for example, and that the 62112 dehydrogenase is a useful target for the identification of compounds for the

modulation of cellular proliferation (e.g. cellular proliferative disorders, including tumors arising from colon, breast, lung or ovarian cells). The specification also teaches, for example at pages 86-90 and in Tables 1-2, that the 62112 dehydrogenase is differentially expressed in lung tumors, breast tumors, ovarian tumors, and colon tumors (among others) versus their normal counterpart tissues. Applicants submit that one of ordinary skill in the relevant art would readily understand the relationship of the differential expression of 62112 protein (e.g. expression in tumor vs. normal tissue) and cellular proliferation disorders, (e.g. tumors arising from lung, breast, ovary, and colon tissues). Applicants point out that this differential expression was determined and confirmed by two separate methods (TaqMan mRNA expression and in situ hybridization), further supporting the Applicants assertion of utility in cellular proliferative disorders. Thus, contrary to the Examiner's assertion, the specification does indeed link the polypeptide of the invention to specific cellular proliferative disorders (e.g. tumors arising from lung, breast, ovary, and colon vs. normal respective tissues).

Moreover, Applicants assert that a showing of specific diseases which are in fact demonstrated to be treatable by the invention is not necessary. The Examiner focuses on the specific biological significance and seemingly the required efficacious use of identified compounds as Applicants' requirement to satisfy the utility requirement. Applicants respectfully submit this focus is undue and improper. Still further, the utility of identification of targets for screening for therapeutics in the pharmaceutical industry is a well established recognized utility for molecules useful in biological functions such as those identified and asserted in the present application as useful (e.g. cell growth and proliferation, cancer).

The Examiner appears to assert that the claimed methods require further determination of efficacy or activity *in vivo*. Applicants respectfully point out that the claimed screening methods do not require any *in vivo* step, but rather recite a method of identifying a compound which binds to a 62112 polypeptide, wherein the compound is capable of modulating cellular growth or proliferation of cancer cells *in vitro*.

In summary, Applicants have identified an acyl-CoA dehydrogenase molecule, named 62112, whose activity as an acyl-CoA dehydrogenase has been confirmed by the studies of Zhang et al. In addition, Applicants have demonstrated differential expression of 62112 in tumor versus normal tissues by two independent methods, and have asserted a use for the claimed invention in identifying compounds which are capable of modulating cellular proliferation disorders. Therefore, Applicants submit that the utilities set forth for the 62112 dehydrogenase of the invention are specific and credible. Applicants also submit that the utilities set forth for the 62112 dehydrogenase of the invention are substantial utilities, since the asserted use to identify modulators of cell growth or proliferation using the provided methods constitutes a real world use. Thus, in contrast to the Examiner's assertions, Applicants submit a utility specific, substantial and credible for methods using the 62112 dehydrogenase has in fact been asserted.

Applicants submit the Examiner has not met the requirement to rebut Applicants asserted utility – no evidence specific to demonstrate Applicants' asserted utility is inoperative, not useful, or contradictory to scientific principles has been presented.

Applicants submit that an effective, credible, specific and substantial utility has been properly asserted in the specification as filed. Therefore, Applicants respectfully believe the Examiner's imposition of the present rejection is improper, and as such the rejection under 35 USC §101 should be withdrawn. Applicants respectfully request reconsideration and withdrawal of the rejection of claims 64-72 under 35 USC §101.

The Rejection of Claims 64-72 Under 35 USC §112, First Paragraph (Enablement) Should Be Withdrawn

Claims 64-72 were rejected under 35 USC §112, first paragraph due to lack of satisfying the utility requirement. For the reasons discussed above, Applicants submit the utility requirement has been met and respectfully request reconsideration and withdrawal of the rejection under 35 USC §112, first paragraph.

CONCLUSIONS

In view of the remarks made herein, Applicants respectfully submit that the rejections presented by the Examiner are now overcome and that this application is in condition for allowance. If in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned.

This paper is being filed timely as a request for a three month extension of time is filed concurrently herewith. No additional extensions of time are required. In the event any additional extensions of time are necessary, the undersigned hereby authorizes the requisite fees to be charged to Deposit Account No. 501668.

Entry of the remarks made herein is respectfully requested.

Respectfully submitted,

November 9, 2005

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APPENDIX A

In re application of:	Meyers, Rachel E., et al		
Application No.:	09/945, 326	Group No.:	1642
Filed:	August 31, 2001	Examiner:	Yu, Misook
For:	62112, A NOVEL HUMAN DEHYDROGENASE AND USES THEREOF		

ALIGNMENT of SEQ ID NO:3 from 09/945,326 and ACAD-9 (GenBank Accession No. BC013354)

gb|BC013354|BC013354 Homo sapiens acyl-Coenzyme A dehydrogenase family, member
9, mRNA (cDNA clone MGC:14970 IMAGE:3935925), complete cds.
Length = 2439

Plus Strand HSPs:

Score = 9315 (1403.7 bits), Expect = 0.0, P = 0.0
Identities = 1863/1863 (100%), Positives = 1863/1863 (100%), Strand = Plus / Plus

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